Docket No.: 60726-A/JPW/GJG/CSN

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Moses Rodriguez and Daren Ure

Serial No.: 09/885,227 Examiner: O. Chernyshev

Filed : June 20, 2001 Group Art Unit: 1646

For : TREATMENT OF CENTRAL NERVOUS SYSTEM DISEASES BY ANTIBODIES AGAINST GLATIRAMER ACETATE

1185 Avenue of the Americas
New York, New York 10036
January 29, 2003

Assistant Commissioner For Patents
Washington, D.C. 20231

SIR:

COMMUNICATION IN RESPONSE TO DECEMBER 3, 2002 RESTRICTION REQUIREMENT AND PETITION FOR ONE-MONTH EXTENSION OF TIME

This Communication is submitted in response to the December 3, 2002 Office Action issued by the United States Patent and Trademark Office in connection with the above-identified application. A response to the December 3, 2002 Office Action was due January 3, 2003. Applicants hereby petition for a one-month extension of time from January 3, 2003 to February 3, 2003. The required fee for a one-month extension of time is $110.00 and a check in this amount is enclosed. Therefore, a response to the December 3, 2002 Office Action is now due February 3, 2003 and this Communication is being timely filed.

On pages 2-4 of the December 3, 2002 Restriction Requirement, the Examiner entered a restriction requirement between claims defining the following allegedly independent and distinct Groups:

I. Claims 1-8 [sic] [1-18], drawn to an antibody to an epitope of COP-1;

II. Claims 19-27, drawn to a method of stimulating

remyelination of axons by contacting the axons with an antibody to COP-1;

III. Claims 28-42, drawn to a method of treating a subject by administration of an antibody to COP-1;

IV. Claim 43, drawn to a method of stimulating remyelination by contacting the axons with COP-1;

V. Claim 44, drawn to a method of treating a subject by administration of COP-1; and

VI. Claims 45-53, drawn to a method of stimulating proliferation of lymphocytes.

If Group III or V is elected, the Examiner further required an election of a disease associated with demyelination of central nervous system axons in claims 38 and 44.

The Examiner alleged that Groups I and (II, III, and VI) are related as product and process of use. The Examiner stated that inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with a another materially different product or (2) the product as claimed can be used in a materially different process of using that product, citing MPEP §806.05(h). The Examiner alleged that in the instant case, the antibodies of Group I could be used in an entirely different manner such as for the purification of polypeptides rather than in the methods of Groups II, III, and VI.

The Examiner additionally alleged that Groups I and (IV and V) are unrelated. The Examiner stated that inventions are unrelated

if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects, citing MPEP §806.04, MPEP §808.01. The Examiner indicated that in the instant case, the Groups are not required one for the other in that the antibodies of Group I are not required for the methods of Groups IV and V.

The Examiner alleged that Groups II, III, IV, V and VI are also unrelated. The Examiner alleged that in the instant case, the Groups are directed to different methods that recite structurally and functionally distinct elements, are not required one for the other, achieve different goals, and therefore allegedly constitute patentably distinct inventions.

The Examiner alleged that because these Groups are distinct for the reasons given above and have acquired a separate status in the art as allegedly shown by their different classification, recognized divergent subject matter and non-extensive literature searches, restriction for examination purposes as indicated is allegedly proper.

In response to the Restriction Requirement, applicants hereby elect with traverse Group I, i.e. claims 1-8 [sic] [1-18], drawn to an antibody to an epitope of COP-1.

However, applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement with respect to Groups I-III and VI. Applicants respectfully direct the Examiner's attention to 35 U.S.C. §121, which states, in part, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." [Emphasis added]. Applicants request that the restriction requirement be withdrawn

with respect to Groups I-III and VI because the Groups I-III and VI are not independent of each other.

Under M.P.E.P. §802.01, "independent," means "there is no disclosed relationship between the subjects disclosed, that is, they are unconnected in design, operation and effect." Applicants maintain that there is a disclosed relationship between Group I and Groups II-III and VI. Group I (antibody to an epitope of COP-1) is related to Group II (method of stimulating remyelination of axons by contacting axons with an antibody to an epitope of COP-1), Group III (method of treating a subject by administration of an antibody to an epitope of COP-1) and Group VI (method of stimulating proliferation of lymphocytes by contacting lymphocytes with an antibody to an epitope of COP-1) in that the methods of Groups II, III and VI use the antibody of Group I. Accordingly, the restriction requirement should be withdrawn with respect to Groups I-III and VI.

Furthermore, under M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. Applicants assert that the withdrawal of the restriction requirement with respect to Groups I-III and VI would not impose a serious burden on the search or examination. A search of the prior art regarding an antibody to an epitope of COP-1 (Group I) would also reveal prior art concerning uses of the antibody, including a method of stimulating remyelination of axons by contacting axons with an antibody to COP-1 (Group II), a method of treating a subject by administration of an antibody to COP-1 (Group III), and a method of stimulating proliferation of lymphocytes by contacting lymphocytes with an antibody to COP-1 (Group VI). Given that it would not be a serious burden on the Examiner if

restriction were not required, the restriction requirement should be withdrawn with regard to Groups I-III and VI.

For all of the above reasons, applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement with regard to Groups I-III and VI.

Furthermore, as the Examiner acknowledged on page 2 of the December 3, 2002 Restriction Requirement, Groups I-III and VI are related as product and process of use. Applicants respectfully direct the Examiner's attention to 37 C.F.R. §1.141(b), which states, "If the process of making and the product are not distinct, the process of using may be joined with the claims directed to the product and the process of making the product, even though a showing of distinctness between the product and the process of using the product can be made." Applicants are not claiming a process of making, so the rule as applied to the subject application indicates that the process of using (Groups II-III and VI) may be joined with the claims directed to the product (Group I), even if a showing of distinctness between the product and the process of using the product can be made, as the Examiner has alleged.

Applicants respectfully point out that if Groups II-III and VI are not examined with Group I, if the product claims of Group I are allowed, use of the claimed product must be included in the same application. Applicants respectfully direct the Examiner's attention to MPEP §806.05(i), which states, "Where the product claims are allowable (i.e., novel and nonobvious), restriction may be required only where the process of making and the product made are distinct (MPEP §806.05(f)); otherwise the process of using must be joined with the process of making and product made, even if a showing of distinctness can be made between product and

process of using (MPEP §806.05(h))" (emphasis added). The MPEP indicates if the product claims are allowable, the only case in which a restriction would be appropriate is where the process of making and the product made are distinct. Applicants are not claiming a process of making. Therefore, if the product claims of Group I are allowed, then claims to the use of the product (Groups II-III and VI), must be joined with the product claims. Rather than solely examining Group I and then adding back Groups II-III and VI after the allowance of Group I, applicants respectfully request that, the Examiner join Group I with Groups II-III and VI.

If a telephone interview would be of assistance in advancing prosecution of the subject application, the undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, other than the enclosed $110.00 surcharge for the one-month extension of time, is deemed necessary in connection with the filing of this Communication. However, if any additional fee

is deemed necessary, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
Assistant Commissioner for Patents
Washington, D.C. 20231

John P. White Date
Reg. No. 28,678